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Stringham

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(54) **AUTOMATIC SAFETY OCCLUDER**

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(60) Provisional application No. 61/150,705, filed on Feb. 6, 2009.

(51) **Int. Cl.**
A61M 5/00 (2006.01)
A61M 1/00 (2006.01)

(52) **U.S. Cl.**
USPC **604/250**; 604/151; 251/4; 251/6

(58) **Field of Classification Search**
USPC 604/118, 246, 249, 250-251; 251/4-5, 251/7, 90, 321, 337

See application file for complete search history.

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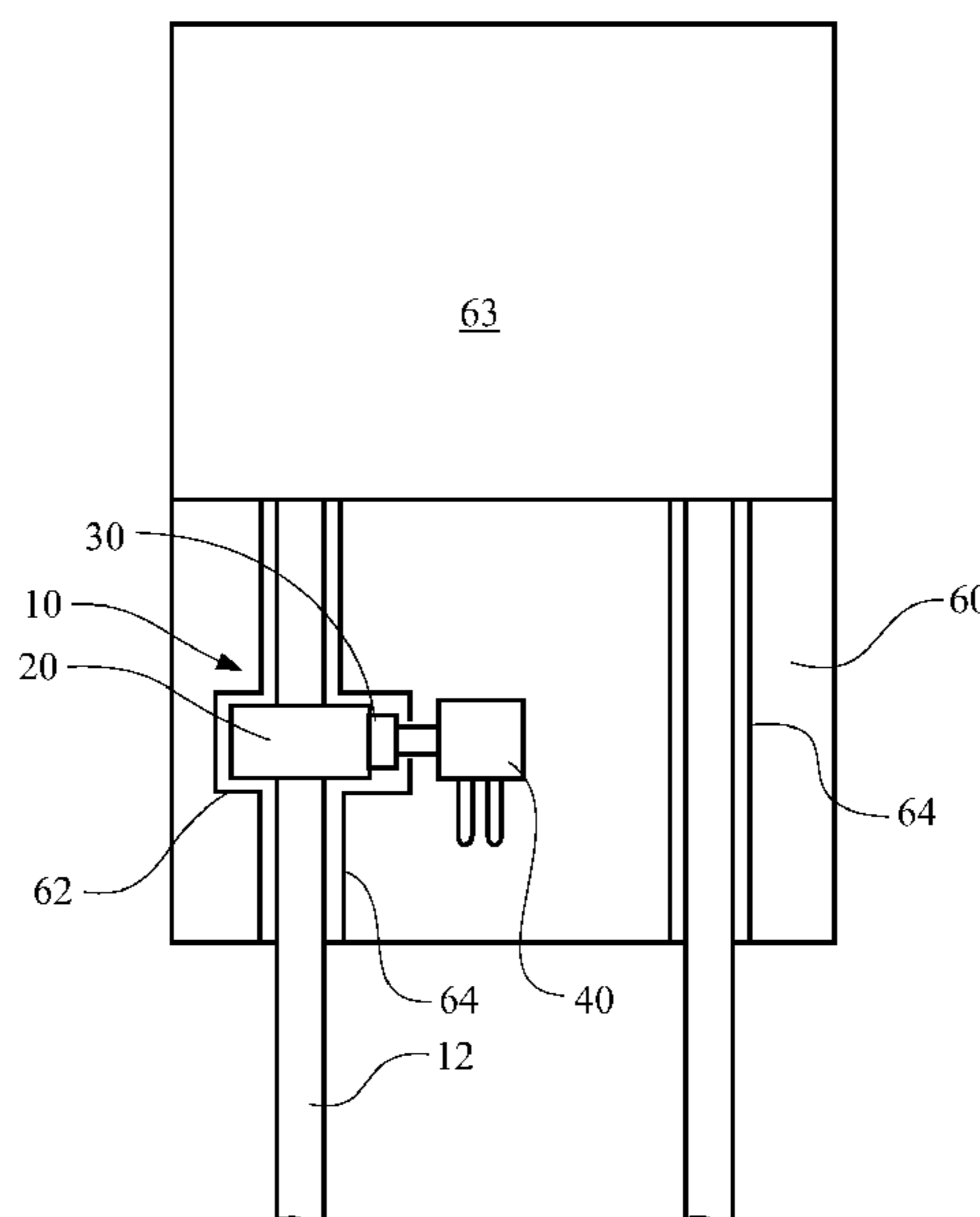
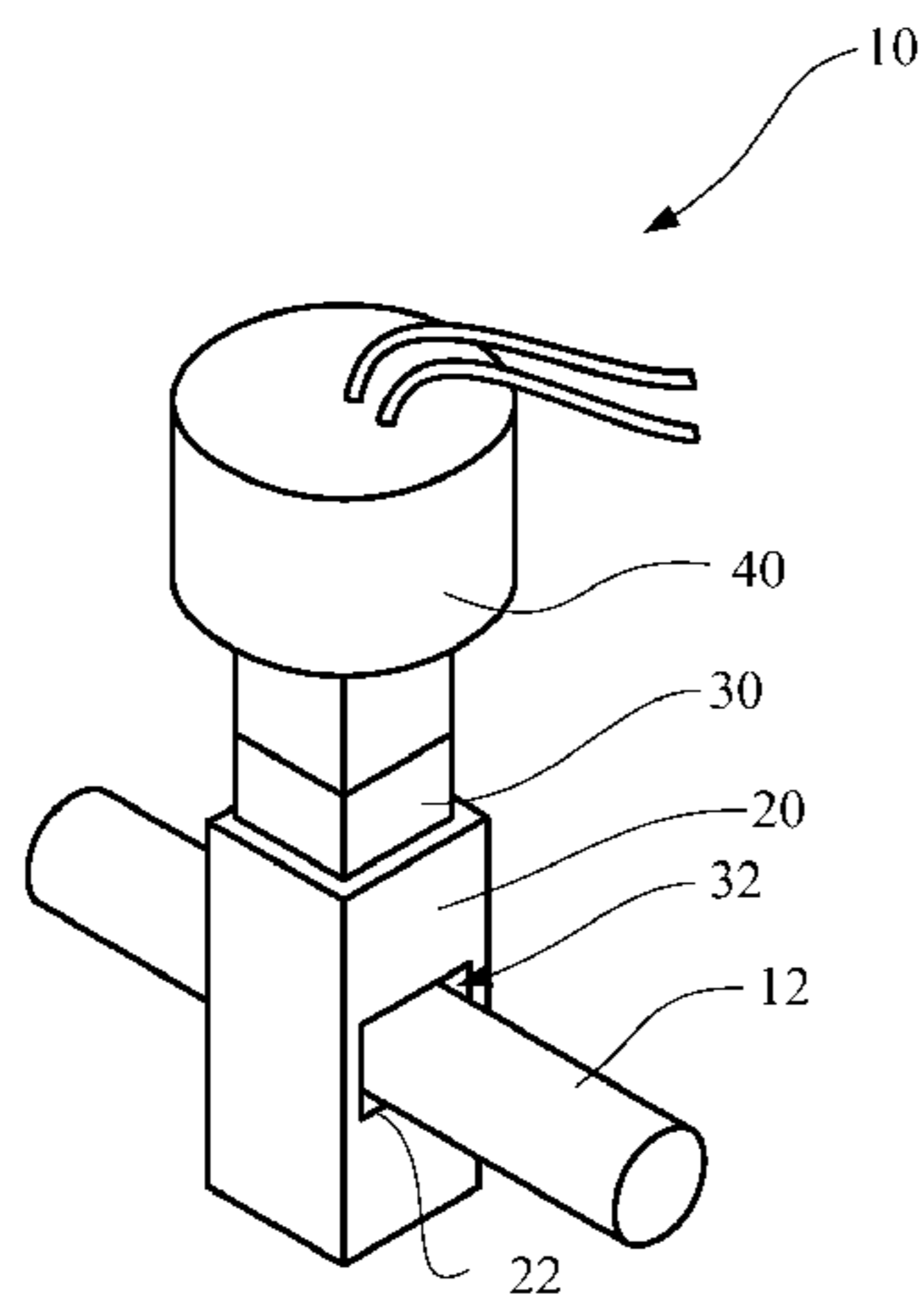
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(57) **ABSTRACT**

An automatic safety occluder provides an occluder for an infusion set that is biased in a closed position until an electrical signal is received that causes the occluder to open. Should the occluder fail to be installed correctly, or if power is removed, the occluder will return to its biased closed position, preventing free flow. The occluder may also be placed in an integrated unit such that the automatic safety occluder may attach to the tubing as a unit.

3 Claims, 7 Drawing Sheets



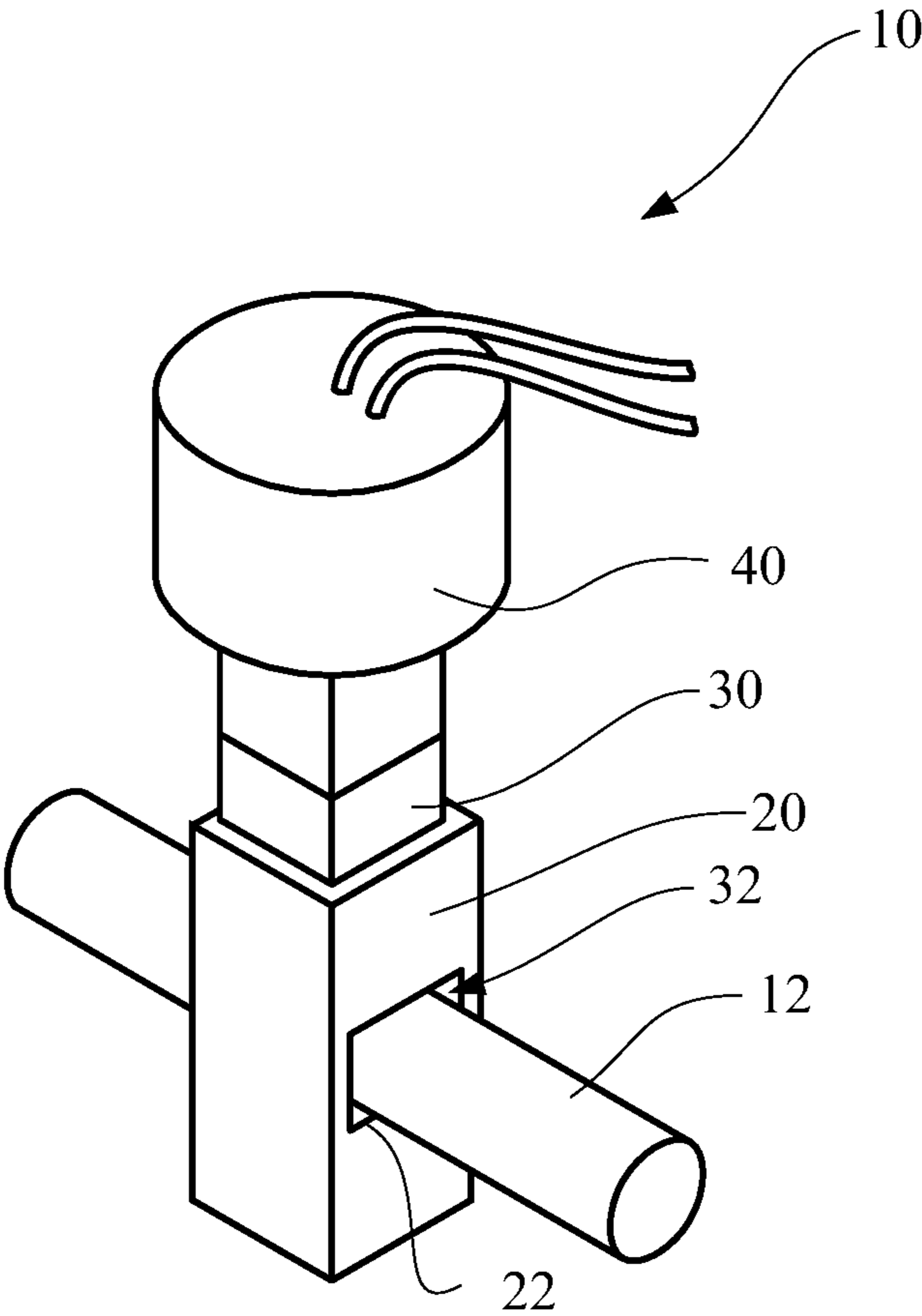


FIG. 1

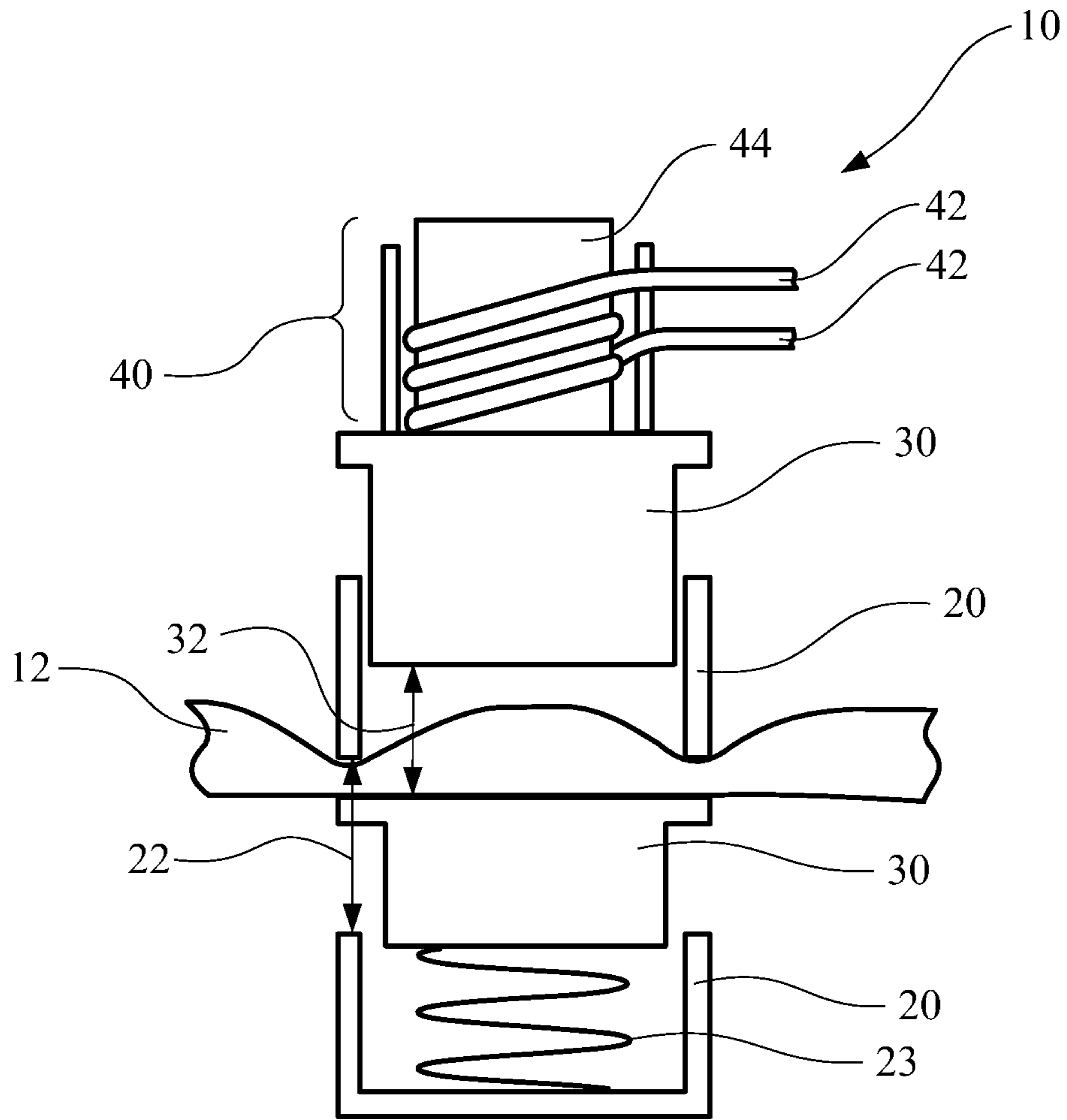


FIG. 2

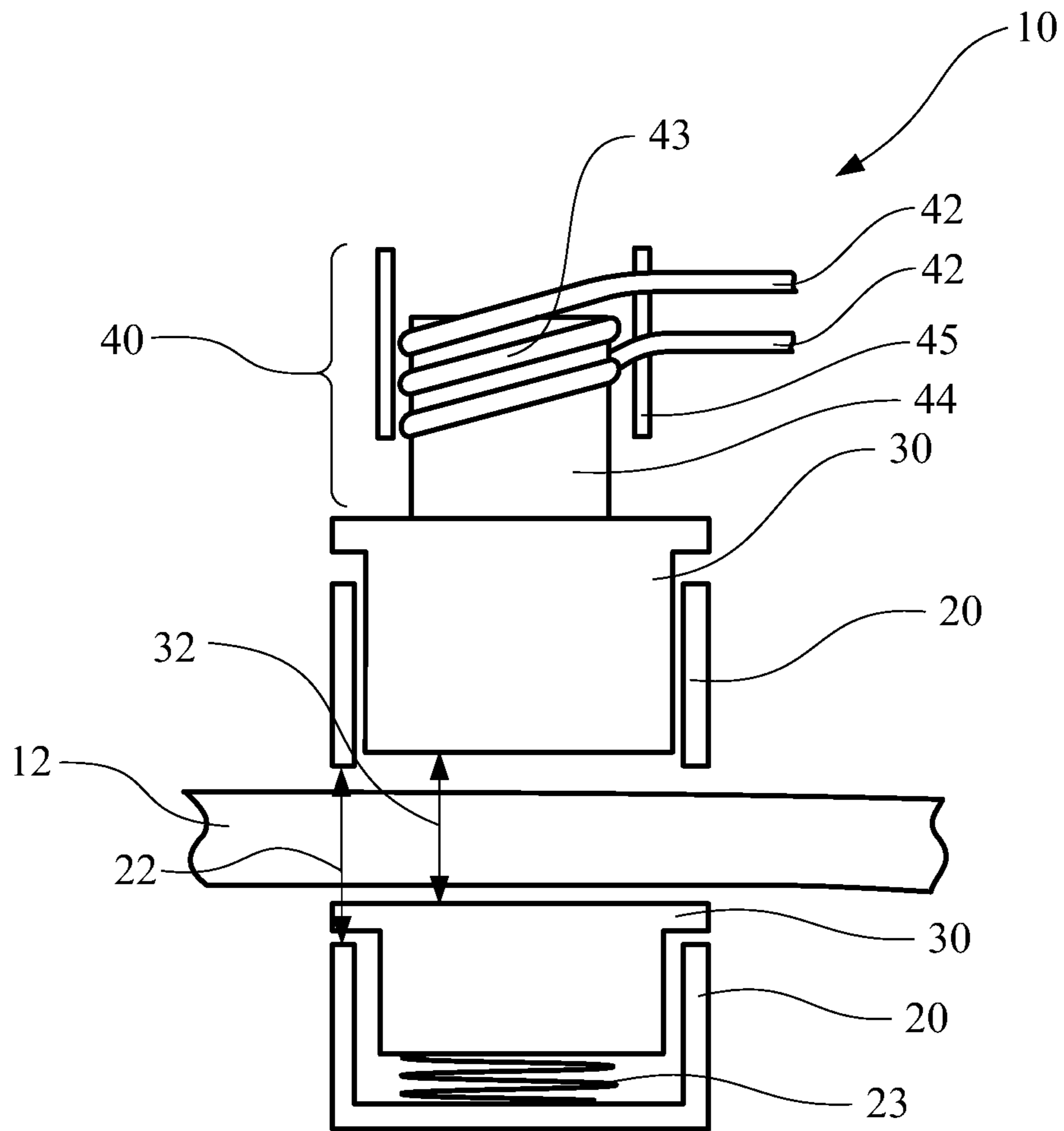


FIG. 3

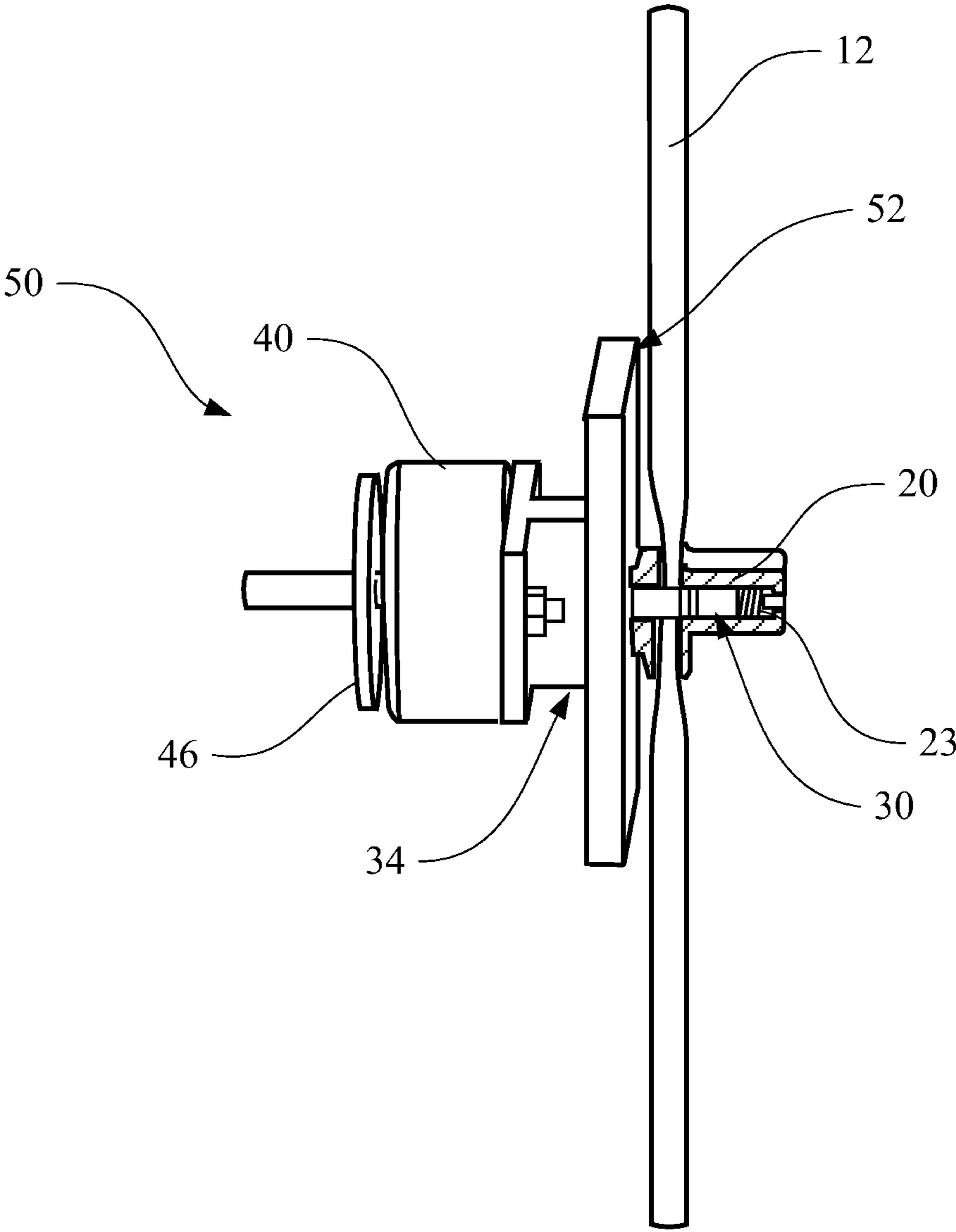


FIG. 4

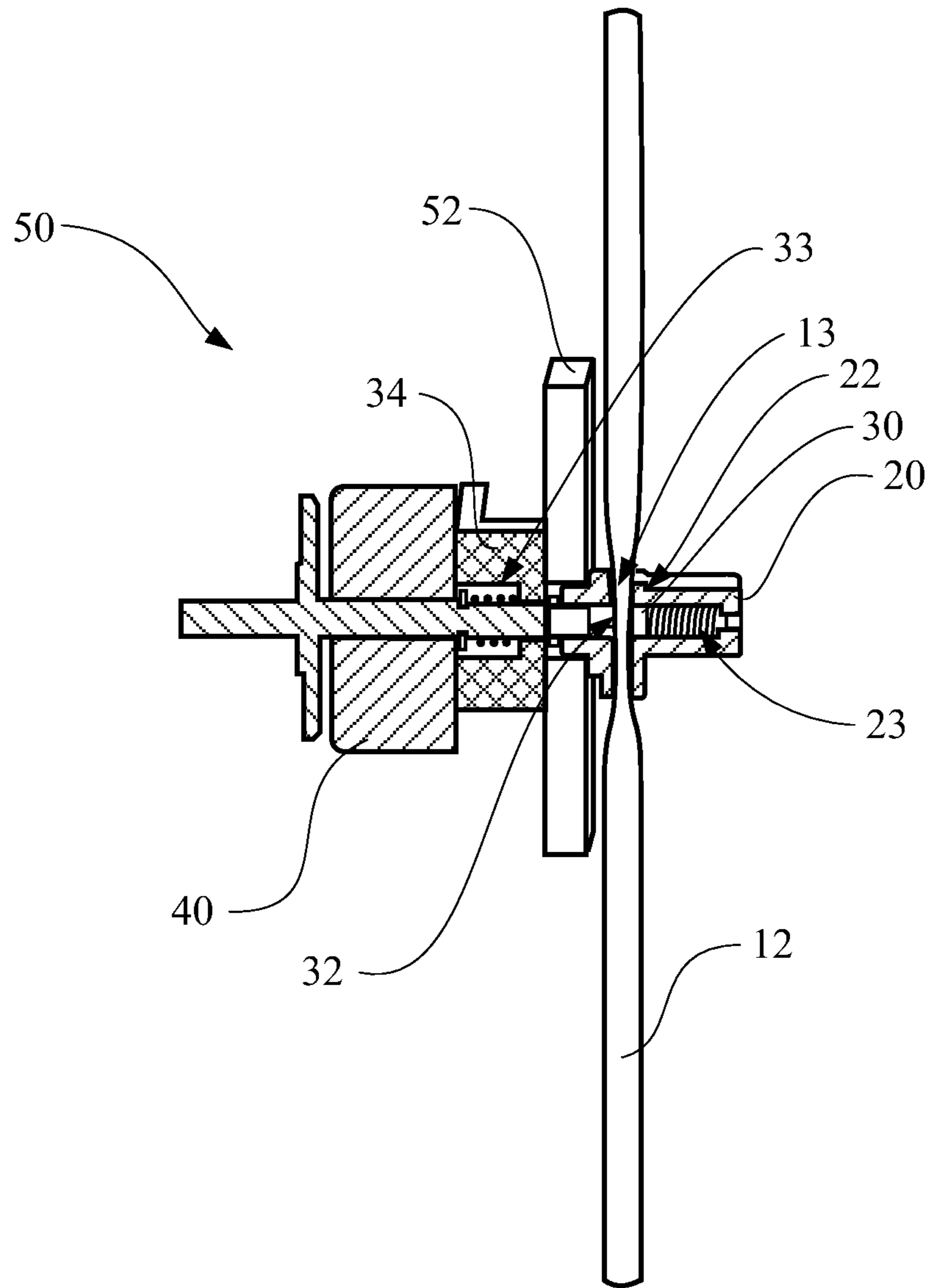


FIG. 5

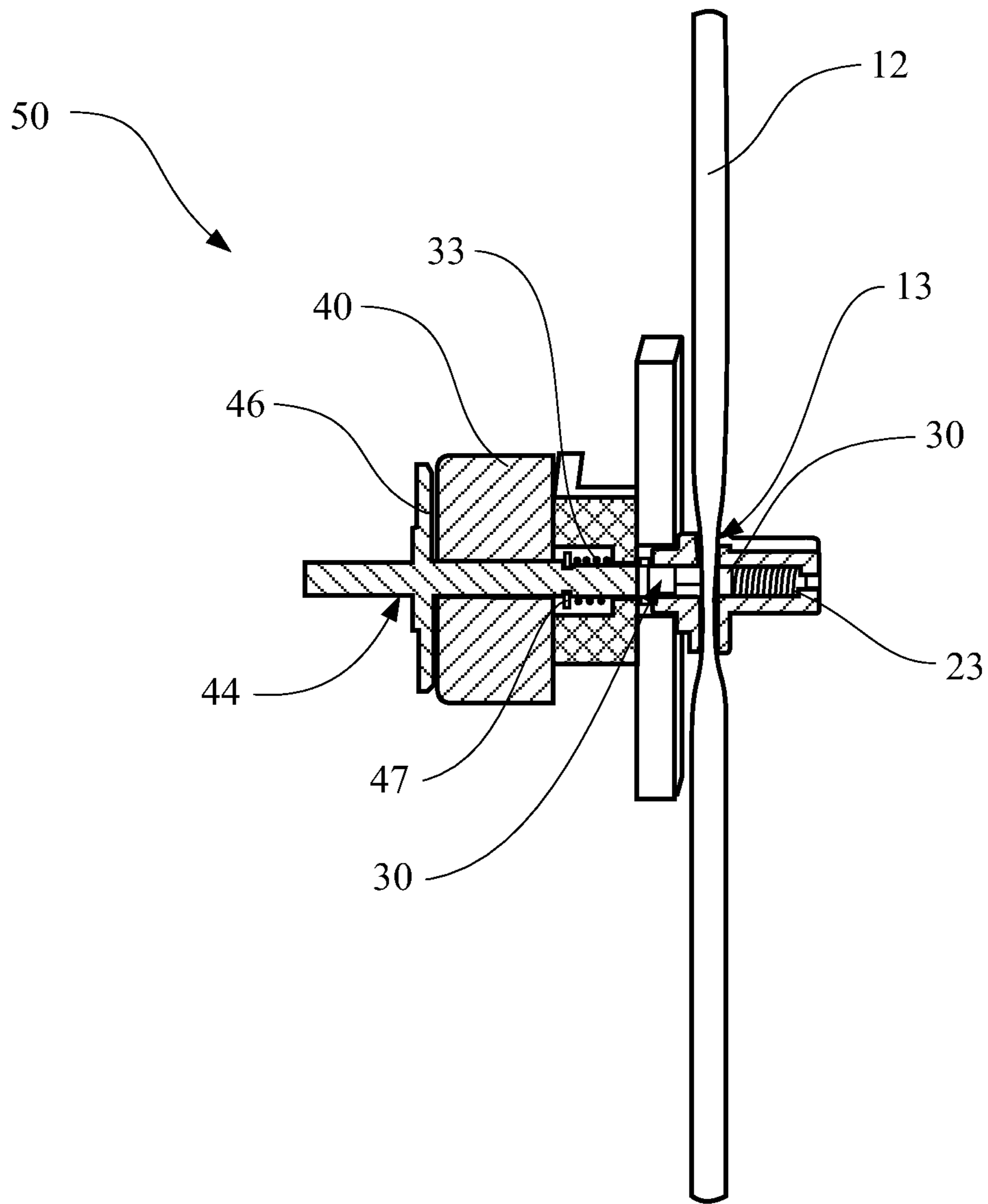


FIG. 6

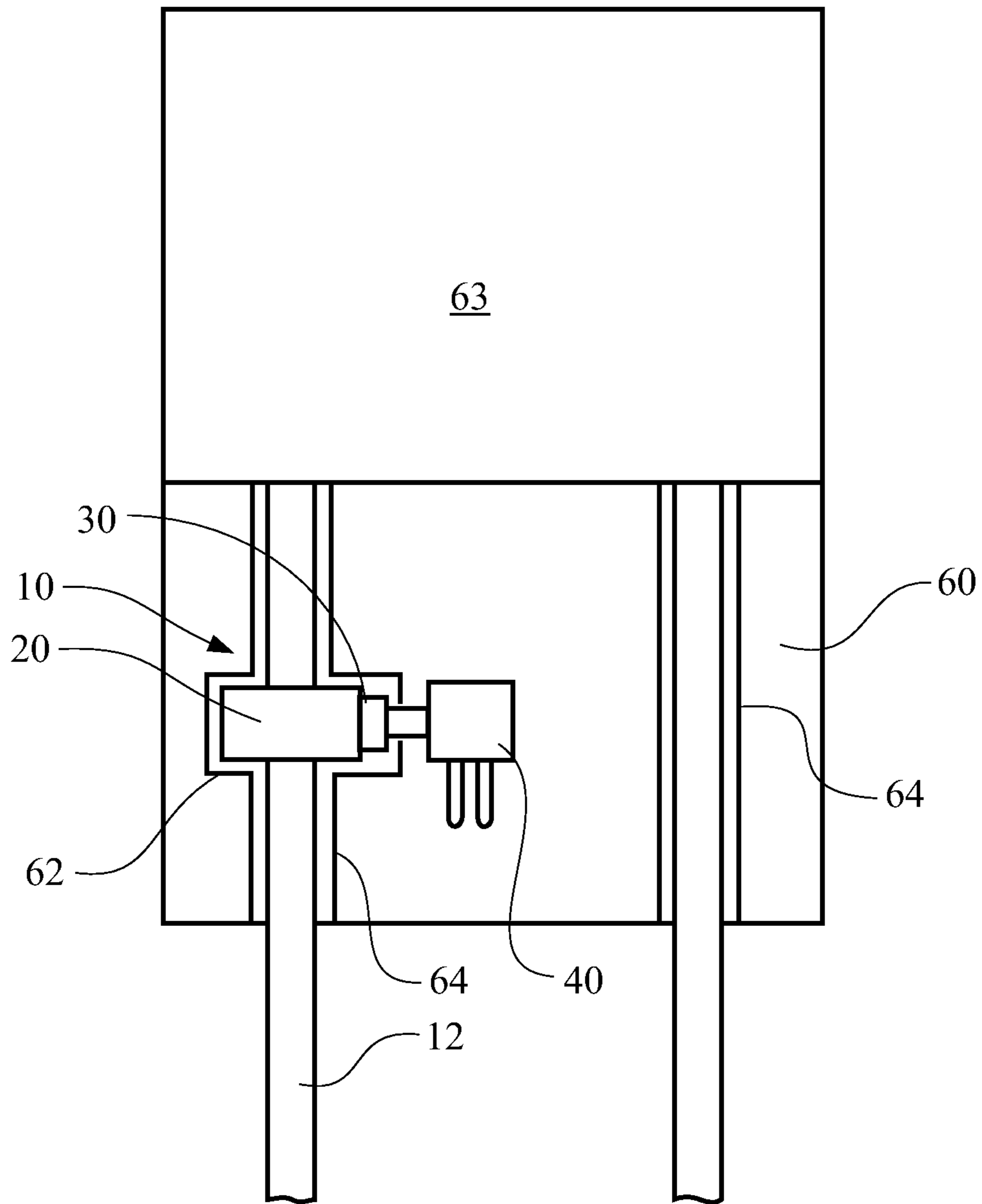


FIG. 7

AUTOMATIC SAFETY OCCLUDER

PRIORITY

The present application is a divisional of U.S. Pat. No. 12/701,467, filed Feb. 5, 2010, now U.S. Pat. No. 7,998,121, and claims the benefit of U.S. Provisional Application Ser. No. 61/150,705, filed Feb. 6, 2009, which are herein incorporated by reference in their entirety.

THE FIELD OF THE INVENTION

The present invention relates to an apparatus and method for selectively preventing and allowing free flow of solutions through a tube. More particularly, the present invention relates to preventing free flow of solutions while administering fluids to a patient such as during I.V. infusion or during enteral or parenteral administration of solutions through an infusion line. More particularly, the present invention relates to an occluder/valve and method of use for infusion sets and the like, wherein the occluder/valve automatically prevents undesirable free-flow of solution through the infusion set while allowing an electrical signal to place the infusion set in a free-flow condition to facilitate the rapid delivery of fluids to a patient.

BACKGROUND

The use of infusion sets to administer solutions to patients is well known in the medical arts. Infusion sets are used for I.V. infusion as well as enteral and parenteral applications, for example. Enteral feeding pumps are used to provide patients with nutrition and medication when they are unable, for a variety of reasons, to eat normally. Parenteral (intravenous) solutions are provided to patients to ensure adequate hydration and to provide needed nutrients, minerals and medication. Often, the infusion set is placed in a free standing arrangement in which gravity forces the solution into the patient. The rate at which the solution enters the patient can be roughly controlled by various clamps, such as roller clamps, which are currently available on the market.

In many applications, it is necessary to precisely control the amount of solution which enters the patient. When this is the case, a regulating device, such as an enteral feeding pump or an IV pump, is placed along the infusion set to control the rate at which the solution is fed to the patient. In applications where a pump, etc., is used, the clamp used to control the flow of the solution (if present on the infusion set) is typically opened to its fullest extent to prevent the clamp from interfering with the proper functioning of the pump. The clamp is opened with the expectation that the enteral feeding pump will control fluid flow through the infusion set. However, emergencies or other distractions may accidentally remove the infusion set from the pump or prevent the medical personnel from properly loading the infusion set in the enteral feeding pump.

When the infusion set is not properly loaded in the pump and the clamp has been opened, a situation known as free-flow often develops. The force of gravity or a pressure differential causes the solution to flow freely into the patient unchecked by the pump or other regulating device. Under a free-flow condition, an amount of solution many times the desired dose can be supplied to the patient within a relatively short time period. This can be particularly dangerous if the solution contains medicine as this could result in an overdose of medication. Free flow can also be dangerous where the patient's body is not physically strong enough to adjust to the

large inflow of solution. There have been numerous occasions in which a patient has died due to the over-infusion of fluid during a given amount of time. Thus, preventing an undesirable free-flow state is highly desirable.

Numerous devices have been developed in an attempt to prevent free flow conditions. Such devices, however, add to the overall cost of the infusion set and some provide only marginal protection against free flow. Others may have other limitations which limit the usefulness of the occluder.

One popular anti-free flow occluder is described in U.S. Pat. No. 5,704,584 (Winterer et al.). The '584 patent teaches an occluder which is disposed around the outside of an infusion set to selectively prevent fluid flow. The occluder is biased into a closed position wherein the occluder stops flow through the infusion set. The biasing can be overcome by manually holding the occluder open, or by mounting the occluder in a pump and then closing a door so that the door holds the occluder open. The '584 patent describes the general use of occluders in infusion pumps.

While preventing unintended free-flow situations is important, there are also times in which a free-flow condition is desired. This may be the case where a patient's heart has stopped or in other emergency situations where quick corrective action is desired. Often medicines will be injected into an IV solution being administered to the patient with the desire that the solution and medicine enter the patient as quickly as possible. If the infusion set uses one of the above referenced occluders, the medical staff must ensure that free-flow conditions are being allowed. This may mean removing the infusion set from the pump in which it is housed and manually holding open the occluder. Obviously, this is not desirable, as each member of the medical staff has important duties during an emergency situation. Thus, it is desirable for medical staff to be able to lock the occluder open in an emergency or other situation in which a free-flow condition is specifically desired.

Several types of occluders can be locked in an open position. One such occluder is biased closed and designed to accept a pin into a pair of apertures to hold the occluder in an open position. Such occluders, however, are disadvantageous because the pin can be lost during the commotion involved with an emergency and the occluder may be left in a biased closed condition.

Another known occluding system uses a spring which is biased to pinch closed the tubing of an infusion set. The spring can be pushed into an open position where it allows flow through the infusion set by pressing down on a locking trigger. The locking trigger can also be moved into a locked position wherein the spring is held in an open position. The occluding system, however, is disadvantageous, as it is relatively bulky. Additionally, if the trigger is disposed in the locked open position, the module cannot be properly loaded into a pump, as the pump door will not close.

There is a need for an occluder which allows for greater control and flexibility in selecting an open or closed occluder position. There is a need for an occluder which may be controlled electronically as well as mechanically, allowing a pump or other device attached to the occluder to selectively allow or prevent flow through an infusion tube. There is a need for an occluder which automatically occludes flow through a tube if power is lost or if the tubing set is removed from the pumping device, preventing the uncontrolled flow of fluids in such a situation. There is also a need for such an occluder which is relatively inexpensive and which is easy to use.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide an apparatus and method for selectively occluding infusion sets to

3

prevent an accidental or undesired free-flow condition, and which can be automatically placed in the off position if power is lost.

According to one aspect of the invention, an occluder is provided which uses an electrical solenoid to operate the occluder. The occluder is biased into an occluding position by a spring internal to the occluder and uses the solenoid to move the occluder into an open position. An electrical signal from an infusion pump or other associated equipment will cause the occluder to open and remain open as is desired. Should the electrical signal stop, the occluder will return to its biased closed position automatically.

These and other aspects of the present invention are realized in an automatic safety occluder as shown and described in the following figures and related description.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments of the present invention are shown and described in reference to the numbered drawings wherein:

FIG. 1 shows a perspective view of an automatic safety occluder;

FIG. 2 shows a partially cut away view of the automatic safety occluder of FIG. 1 in its biased closed condition;

FIG. 3 shows a partially cut away view of the automatic safety occluder of FIG. 1 in its active open condition;

FIG. 4 shows a perspective view of another automatic safety occluder;

FIG. 5 shows a cut-away view of the automatic safety occluder of FIG. 4 in its biased closed condition;

FIG. 6 shows a cut-away view of the automatic safety occluder of FIG. 4 in its active open condition; and

FIG. 7 shows a diagram of the automatic safety occluder of FIGS. 1 and 4 and an infusion set loaded into a pump.

It will be appreciated that the drawings are illustrative and not limiting of the scope of the invention which is defined by the appended claims. The embodiments shown accomplish various aspects and objects of the invention. It is appreciated that it is not possible to clearly show each element and aspect of the invention in a single FIGURE, and as such, multiple figures are presented to separately illustrate the various details of the invention in greater clarity. Similarly, not every embodiment need accomplish all advantages of the present invention.

DETAILED DESCRIPTION

The invention and accompanying drawings will now be discussed in reference to the numerals provided therein so as to enable one skilled in the art to practice the present invention. The drawings and descriptions are exemplary of various aspects of the invention and are not intended to narrow the scope of the appended claims.

Turning now to FIG. 1, a perspective view of an occluder 10 disposed upon a piece of tubing 12 of an infusion set is shown. The infusion tubing 12 is for carrying a fluid to a patient, and also includes connectors and other necessary parts. If used in an infusion pump, the infusion set may often include an upstream tube connectable to a fluid reservoir, a pump engaging section of tubing 12, and a downstream tube which is connected to the patient. The pump engaging tubing is connected to the upstream and downstream tubing, and is typically a more resilient tubing that functions better in a pump and occluder 10. The occluder 10 includes a body 20, plunger 30 and actuator 40. The body 20 and plunger 30 have apertures 22 and 32 therethrough, and the tubing 12 passes

4

through the passages 22 and 32. When the plunger 30 is pressed into the body 20, the apertures 22 and 32 are aligned (as shown), allowing flow through the tube 12. A spring presses the plunger away from the body, causing the apertures 22, 32 to become misaligned and causing the tubing to be pinched between the walls forming the apertures.

The actuator 40 is an electrical solenoid. The solenoid 40 and/or plunger 30 is biased into a closed position which misaligns the apertures 22, 32 and prevents flow, typically by a compression spring disposed in the body of the occluder 10. As such, when the solenoid 40 is not receiving an electrical signal, the solenoid 40 allows the plunger 30 and body 20 to pinch the tubing 12 closed. The solenoid 40 may have a spring therein to bias the solenoid into a non-actuated position such that the friction involved with actuating the solenoid does not interfere with the operation of the occluder 10. When the solenoid 40 receives an electrical signal to open, it presses on the plunger 30 and causes the body aperture 22 and plunger aperture 32 to align and thereby cease pinching the tubing 12 closed. Should the power be removed from the solenoid 40, the body 20 and plunger 30 will return to their biased closed state.

According to one aspect of the invention, the piston of the solenoid 40 may be attached to the plunger 30 and the solenoid 40 is not attached to the body of the occluder 20. When the infusion set and occluder 10 are loaded in an infusion pump (60, FIG. 7), the body of the solenoid 40 is disposed adjacent a retaining structure in the pump, such as a wall. Thus, when an electrical signal is applied to the solenoid 40, the solenoid expands and presses against the pump body (i.e. the retaining wall) and the plunger 30, allowing flow through the occluder 10. If the occluder 10 and solenoid 40 are removed from the pump, the occluder 10 is closed regardless of whether electricity is applied to the solenoid, since only the solenoid piston and not the solenoid body is connected to the occluder.

According to another aspect of the invention, the solenoid 40 may be part of the infusion pump 60. The plunger 30 is then disposed adjacent the solenoid 40 when the infusion set and occluder 10 are loaded into the pump, allowing actuation of the solenoid to actuate the occluder 10 by compressing the occluder plunger 30. The solenoid 40 presses against the plunger 30 when an electrical signal is applied to the solenoid 40. Again, the occluder 10 is closed if removed from the pump since the solenoid 40 remains as part of the pump. Similarly, should the plunger 30 or body 20 be incorrectly installed relative to the solenoid 40, the automatic safety occluder 10 will remain biased in the closed state.

The use of the occluder 10 in combination with a solenoid 40 is advantageous for several reasons. Prior occluders allowed flow through the tubing once the infusion set was mounted into the pump, regardless of the operational state of the pump. The present occluder 10 and solenoid 40 allows the pump electronics to control the operation of the occluder beyond the simple mounting state of the occluder. Thus, if flow must be stopped due to a pump error or air bubbles in the solution, the pump 60 may close the occluder 10 to prevent flow by removing any electrical signal from the solenoid 40. The occluder 10 may thus be closed faster than the pump 60 may stop. This makes the occluder 10 more reliable in preventing flow through the tubing 12.

Turning now to FIG. 2, a cut away view of the occluder 10 in its biased closed state is shown. When the solenoid 40 is not active, a spring 23 biases the plunger 30 upwardly, pinching the tubing 12 between the plunger 30 and the body 20 and preventing flow within the tubing 12. Typically, the occluder 10 uses a conventional push-type solenoid 40 to actuate the

5

occluder. Such a solenoid extends a piston **44** therefrom when an electrical signal is applied to the solenoid and contains an internal spring to retract the piston **44** in the absence of an electrical signal. When the solenoid **40** is not receiving an electrical signal, the solenoid piston **44** is retracted into the solenoid body and away from the occluder body **20** and plunger **30**, allowing the spring **23** to pinch the tubing **12** closed. The lack of signal may be deliberate, as in a desire to close the automatic safety occluder, or by mistake, such as an accidental breaking of the signal wires **42**. In such an arrangement, the occluder **10** provides additional safety in that it fails into a closed position should there be a problem with the solenoid control wires. Similarly, a push-pull solenoid may be used where open and closed positions are actively driven, but should a failure occur, the automatic safety occluder **10** will return to the closed position due to the bias.

Turning now to FIG. **3**, a cut away view of the occluder **10** in an open position is shown. An electrical signal is applied to the solenoid **40** via wires **42**, causing an electromagnetic field within the solenoid to extend the piston **44** and thereby press on the plunger **30** and overcome the bias of the spring **23**. The plunger **30** moves relative to the body **20** such that the plunger aperture **32** lines up with the body aperture **22**. The occluder **10** no longer pinches the tubing **12**, allowing flow through the tubing.

Turning now to FIG. **4**, a perspective view of another occluder and solenoid, designated generally at **50**, is shown. The occluder **50** accepts a tubing **12** and functions in a manner similar to that discussed above to selectively allow or prevent flow through the tubing. The occluder **50** includes a registration member **52** which aids in the positioning of the body **20** relative to the solenoid **40**, tubing **12**, and plunger **30**. Additionally, the registration member **52** may be designed to aid in properly loading the occluder **50** into a pump **60**. In such a case, the registration member would match an opening in the pump or otherwise physically engage the pump body. The solenoid **40** and associated members (**40**, **46**, **34**, **52**, **33**) can be built into the pump **60** so that it is permanently attached to the pump. In such a design, the registration member **52** may include structures to ensure proper alignment of the solenoid **40** with the occluder body **20**, such as a recess in the registration member **52** which receives a projection on the solenoid **40**. The occluder body **20**, plunger **30**, and spring **23** typically are permanently attached to the tubing **12** and make up part of the disposable tubing set. The plunger **30** is biased in the closed position by a return spring **23** mounted within a spring housing **34**.

As shown, the solenoid **40** interfaces with the body **20** and plunger **30**. An occluder unit as shown has the advantages of a reduced risk of alignment error between the body **20**, plunger **30** and solenoid **40**, and reduced risk of misalignment within a pump.

Turning now to FIG. **5**, a partially cut-away view of the occluder **50** of FIG. **4** is shown. The occluder **50** is shown in its biased closed condition. The return spring **23** pushes the plunger **30** such that it pinches the tubing **12** between the edges of the body aperture **22** and the plunger aperture **32**. The bias caused by the plunger return spring **23** and the solenoid return spring **33** ensures that whether or not the solenoid is actively driven closed, the occluder **50** will remain in a closed position to prevent free flow through the tubing lumen **13** absent an affirmative electrical signal to open the occluder **50**.

Turning now to FIG. **6**, a cut-away view of the occluder **50** of FIG. **4** is shown. The occluder **50** is shown in its active open condition. When the solenoid **40** receives an electrical signal to open, the solenoid applies a force with the piston **44** to the

6

plunger **30** which is higher than the force applied by the return spring **23**. The plunger **30** moves to release the tubing **12** and allow flow through the tubing lumen, indicated at **13**. In one embodiment, the movement of the solenoid piston **44** is limited by an upper ring **46** and a lower ring **47** connected to the piston **44**. As shown, the lower ring **47** provides both a positive stop for the plunger **30** and a stop against which the spring **33** pushes to restore the solenoid to a non-actuating position.

Turning now to FIG. **7**, a schematic diagram of an occluder **10** in an infusion pump **60** is shown. The body **20** and plunger **30** are located on tubing **12** as part of an infusion set. The tubing **12** is loaded into the pumping head **63**. Where the solenoid **40** is formed as part of the pump **60** separate from the occluder **10**, the occluder **10** is placed within a recess **62** in the pump body that places the body **20** and plunger **30** in contact with the solenoid **40**. As discussed, a registration member **52** may be used to ensure alignment of the occluder **10** with the pump **60** and with the solenoid **40**. Where the solenoid **40** is integrated into the occluder **10**, the body **20**, plunger **30**, and solenoid **40** are placed within the recess **62**. The solenoid **40** is electrically connected to the pump **60** such that the pump can control the occluder **10** via solenoid **40**. The tubing **12** is placed inside of a channel **64**.

The solenoid driven occluder **10** provides many advantages over the prior art occluders. Should a pump failure or other error occur, the pump **60** may automatically cut power to the solenoid **40** and thereby close the occluder **10**. Similarly, if system power is lost, the occluder **10** will automatically be closed, since any loss of power to the solenoid **40** will cause the occluder to return to its closed bias and will prevent further fluid flow. If the tubing **12** and occluder **10** are accidentally removed from the pump **60**, the occluder **10** will automatically be closed whether or not electrical power is removed from the solenoid **40**. Without force from the solenoid **40** to overcome the bias, the body **20** and plunger **30** will be forced into a biased closed state. The use of an electric solenoid **40** to control the occluder **10** allows the occluder to function as a flow control device, rather than simply an anti-freeflow device.

The automatic safety occluder **10** may be configured to work with different pumps. These may include peristaltic pumps, finger pumps, infusion or syringe pumps, or other methods of moving liquids through tubing.

There is thus disclosed an improved automatic safety occluder. It will be appreciated that numerous changes may be made to the present invention without departing from the scope of the claims.

What is claimed is:

1. A method of selectively preventing flow through an infusion set comprising:
 - selecting an infusion set, the infusion set having a tube through which fluid is delivered and an occluder disposed on the tube;
 - selecting a pump, the pump having an electric solenoid; mounting the infusion set and occluder in a pump such that the occluder is disposed adjacent the solenoid; and selectively sending an electrical signal to the occluder to selectively allow flow through the occluder.
2. The method of claim **1**, wherein the pump has a recess therein for receiving the occluder and wherein the solenoid is disposed in communication with the recess.
3. The method of claim **1**, wherein the method comprises selecting an infusion set with an occluder comprising:
 - a body having a passage therethrough;
 - a plunger movable within the body and having a passage therethrough;

7

8

the tube located in the body passage and the plunger passage;

wherein the plunger is movable between a first position wherein the body passage and the plunger passage are in alignment to allow flow through the tube and a second position wherein the tube is pinched between the body passage and the plunger passage; and

a biasing member disposed between the body and the plunger to bias the plunger into the second position.

5

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10